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CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER	
YOUNG, MICAH PAUL	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/616,884
Filing Date: July 10, 2003
Appellant(s): HATCHER ET AL.

David E. Rodriguez
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/19/10 appealing from the Office action mailed 9/25/09.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-44 were pending; claim 40 has been canceled and claims 1-10 have been withdrawn. Claims 11-39 and 41-44 stand rejected. Claim 43 is objected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

5,591,453	DUCHEYNE et al	01-1997
5,711,960	SHIKINAMI	01-1998
5,721,049	MARCOLONGO et al	02-1998

6,328,990 DUCHEYNE et al 12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13, 21-25, 28, 30, 34, 36, 37, 39, 41, 42 and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Ducheyne et al (USPN 6,328,990 hereafter '990).

The '990 patent teaches a bioactive glass composite comprising at least one biocompatible polymer and a bioglass (abstract). The biocompatible polymer comprises poly(lactic co-glycolic acid) and polyvinyl alcohol (col. 3, lin. 35-44, claim 1). The bioglass includes at least one calcium molecule and at least one phosphorous molecule in an amorphous form (col. 3, lin. 1-20). The composite is in the form of microspheres (claims). The microspheres include drugs (claims 7-10). The composites are used as a scaffold for tissue engineering and implantation (col. 6, lin. 5-53). The immersion process forms an amorphous glass material support matrix. The composite is formed by mixing the polylactic acid, with the glass component comprising at least one calcium molecule, one phosphorous molecule and an inorganic gelled alkoxysilane (col. 2, lin. 55-57). The mixture further comprises polyvinyl alcohol and is hydrolyzed (col. 3, lin. 35-45). This all occurs at room temperature far below 200

degrees Celsius (***Ibid.***). The microspheres can both encapsulate an active agent or act as a substrate for agents (col. 6, lin. 10-30). These disclosures render the claims anticipated.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17, 28-32, 34, 35, 36, 38, and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcolongo et al (USPN 5,721,049 hereafter '049).

The '049 patent teaches a composite material comprising bioactive glass in the form of fibers (abstract). The composite comprises a biocompatible polymer such as a polysulfone (Example III). The bioactive glass comprises at least on calcium molecule and at least one phosphorous molecule, as well as a gellable alkoxysilane (Example I). The glass can further included adjuster compounds such as minor amounts of an aluminum compound (Table I and II). The glass is extruded at high temperature resulting in an amorphous glass material (col. 5, lin. 35-50). The process forms fibers that are 50 microns in diameter (col. 7, lin. 5-15, claim 8) and useful for implantation (col. 13, lin. 5-10). The implants show excellent strength and tissue interaction with tissue in growth after several weeks without the aid of growth factors (col. 14, lin. 23-47). The fibers can be arranged into an orderly support matrix; that is an interpenetrating fibrous network (Example II and III).

Regarding the composite at its ability to allow for the proliferation of stem cells, it is the position of the Examiner that these limitations are merely recitations of a future intended use. The claims recite that the "cells when seeded" will proliferate, meaning the composite is not yet seeded and as such any proliferation would be an inherent feature of the composite. The composite of the instant claims comprises a bioactive glass materials and biocompatible polymers, while the '049 patent teaches an identical composite. Since a compound and its

properties cannot be separated, and the composite of the '049 patent is identical to that of the instant claims, it is the position of the Examiner that the composite of the '049 patent would also proliferate any seeded cells.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the instant claims are defined by a composite comprising a biocompatible polymer and a bioactive glass. The '049 patent teaches a composite material comprising a biocompatible polymer polysulfone and a bioglass (comprising a calcium and phosphate molecular species). The '049 patent meets the structural limitations of the claims and thus anticipates the instant claims.

These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 13, 21-29, 34-39, 41, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ducheyne et al (USPN 6,328,990 hereafter '990) in view of Ducheyne et al (USPN 5,591,453 hereafter '453).

As discussed above the '990 patent discloses a bioglass composite comprising bioglass and a biocompatible polymer. The reference discloses a biocompatible polymer combined with a bioactive glass component comprising at least one calcium molecule and at least one phosphorous molecule. Although the '990 patent discloses the inclusion of drugs, the reference is silent to the specific proteins of the instant claims. The combination of specific proteins into a bioglass composite is well known in the art as seen in the '453 patent.

The '453 patent discloses a bioglass composite material and a method of incorporating biologically active molecules into the matrix (abstract). The bioglass comprises an inorganic alkoxysilane base material, tetramethylorthosilane, combined with a calcium molecule and a phosphorous molecule (col. 13, lin. 18-col. 15, lin. 16). The components are mixed and hydrolyzed forming particles (***Ibid.***). Biologically active molecules are incorporated in to the matrix including bone morphogenic protein (BMP) and platelet derived growth factor (PDGF) (col. 10, lin. 47-68). The composite can be used for implantation and to aid in repair of bone or

other tissues, as a prosthetic device (col. 10, lin. 8-32). The porosity is controlled by the ratio of components. This porosity affects the sustained release of the biologically active molecules (col. 14, lin. 40-50). It would have been obvious to incorporate biologically active proteins as described by the '453 patent into the composite of the '990 patent in order to improve the bone and tissue growth of the patient after implantation.

With these things in mind it would have been obvious to combine the biologically active molecules of the '453 patent into the bioglass based composite of the '990 patent in order to increase the efficacy of tissue growth after implantation of the composite. This combination would have been obvious since both patents teach that active agents can be incorporated into bioglass based composites and used as implants for tissue repair, specifically bone repair. It would have been obvious to combine the prior art with an expected result of a bioglass based composite with sustained release of biological molecules that aid in and speed up tissue repair.

Claims 11, 12, 14, 18-20, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ducheyne et al (USPN 6,328,990 hereafter '990) in view of Shikinami (USPN 5,711,960 hereafter '960).

As discussed above the '990 patent discloses a bioglass composite comprising at least one calcium molecule and at least one phosphorous molecule, combined with a biocompatible polymer. The composite can be in the form of microspheres that are coated with a drug or can be coated to another substrate. The reference is silent to a specific fiber structure as the instant claims however this fiber structure is common in the art and the bioactive glass would have been

an obvious addition to a fiber substrate structure in order to encourage tissue growth. This can be seen in the '960 patent.

The '960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, lin. 50-61). Carriers for the scaffold include further biocompatible polymers such as cellulose gums and gelatin (col. 12, lin. 15-35). The bioactive glass is coated on the surface of the polymers (col. 18, lin. 29-42), and the bioactive glass polymers comprise calcium and phosphorous molecules (co. 17, lin. 45-col. 18, lin. 9). From the figures it is clear the scaffold in orderly with the fibers being placed evenly apart in order to create a scaffold configuration (Figures).The fiber scaffold has a void fraction (porosity) of 20-90% (claim 2). Though silent to specific number the fibers are arranged in an orderly fashion and appear to touch leaving the space between them less than 25 microns (Figures). It would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to ensure increase tissue growth and reaction upon implantation.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with

evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). In the instant case, the prior art discloses a structurally complete composite that is identical to that of the instant claims. As discussed above the '990 patent discloses a composite material comprising a biocompatible polymer and a bioglass compound.

With these things in mind it would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to increase the implants ability to react with surrounding tissue upon implantation, as well as encourage tissue in growth. The '960 patent teaches that the surface of the fiber mesh scaffold should be coated with bioactive glass for the expressed purpose of increasing tissue growth. The bioactive glass composite of the '990 patent accomplishes this end. It would have been obvious to combine the prior art in order to increase tissue growth at the implantation site. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments.

(10) Response to Argument

Applicant argues that:

(1) The '990 patent does not anticipate the instant claims since it does not meet each and every limitation of the claims, specifically the non crystalline nature of the phosphorous component.

Applicant argues that the '990 patent does not meet the limitations of the claim and in fact teaches a crystalline bioactive glass formulation. Applicant argues that since the bioglass is incubated for at least a 1 day the resultant is crystalline. However, Applicant is directed to col. 3, lin. 1-3, where immersion for 6 hours results in an amorphous bioglass composition. Since the

bioglass composite can be incubated from 1 hour to 3 weeks, it is well within the level of skill in the art to form amorphous crystal free bioglass composites. Further the '990 patent teaches a bioactive glass composite identical to the instant claims, comprising at least one biocompatible polymer and a bioglass (abstract). The biocompatible polymer comprises poly(lactic co-glycolic acid) and polyvinyl alcohol (col. 3, lin. 35-44, claim 1). The bioglass includes at least one calcium molecule and at least one phosphorous molecule in an amorphous form (col. 3, lin. 1-20). The composite is in the form of microspheres (claims). The microspheres include drugs (claims 7-10). The composites are used as a scaffold for tissue engineering and implantation (col. 6, lin. 5-53). The composite comprise the same components combined in the same way for the same purpose. Regarding the reaction limitation it is the position of the Examiner that the '990 patent teaches that the polymer and bioglass are reacted together in order to form the composite. Applicant argues that neither the polymer nor the bioglass have the appropriate functional reactive groups along their chain, however the components are identical to the instant claims and would have any and all chemical structures required. Further Applicant is directed to claim 11, where the polymer and bioglass are combined with an alcohol, in a reaction. This combination is specifically defined in the instant specification as a sufficient reaction to meet the instant claims. As such the claims remain anticipated.

(2) The '049 patent does not anticipate the instant claims since it does not meet each and every limitation of the claims, specifically the reacting limitation of the instant claims.

Applicant argues that the polymer and bioglass of the '049 patent are not reacted and therefor the patent does not anticipate the instant claims. Applicant defines "reacted together" as any means of bonding the two components. In each of the Examples of the '049 patent the

bioglass and polymer material are heat pressed together forming a bond between the components forming the composite. The polymer is intermingled with the glass such that when implanted into bone, new bone tissue grows and is bonded to the polymer taking the place of the bioglass. As defined by Applicant the '049 patent teaches a bioglass composite comprising calcium, phosphorous molecules that are reacted (bonded with) a polymer (Example 1). For these reasons the claims remain anticipated.

(3) The combination of the '990 patent with the '453 patent does not obviate the instant claims since it does not teach or suggest the reaction of the instant claims.

Applicant argues that neither the '990 patent nor the '453 patent disclose a reaction of a bioglass composite formed from a reaction. First Applicant is reminded that the claim is drawn to a product that is defined by its compositional components and not by the process of manufacture. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). In the instant case, as discussed above the '990 patent clearly teaches that the calcium and phosphate molecules are reacted with the polymer in an alcohol solution (claim 11). Also the '453 patent discloses sol-gel composite formulation comprising calcium and phosphate molecules identical to those used in the instant

claims and specification. Further the sol-gel composite of the '453 is formulated in an identical hydrolysis process as disclosed in the instant specification [0058 of instant specification].

The combination would have been obvious since both patents disclose similar composition comprising similar components; specifically calcium and phosphate molecules reacted with biologically active polymers. The '990 patent is silent to the specific proteins of the instant claims, however the '453 patent disclosing a similar sol-gel composite discloses bone morphogenic proteins mixed into the sol-gel composite. The '990 patent is suggestive of proteins, while the '453 establishes that the specific protein are well known in the art to be combined into a sol-gel composite comprising calcium and phosphate molecules. This combination would have been obvious since both patents teach that active agents can be incorporated into bioglass based composites and used as implants for tissue repair, specifically bone repair. It would have been obvious to combine the prior art with an expected result of a bioglass based composite with sustained release of biological molecules that aid in and speed up tissue repair. For these reasons the claims remain obviated.

(4) The combination of the '990 patent and the '960 patent does not obviate the instant claims since the '960 patent does not teach that the calcium and phosphorous molecules are not crystalline.

As discussed above the '990 patent clearly discloses sol-gel composite comprising calcium and phosphorous molecules that are not crystalline. Applicant argues that the calcium and phosphorous molecules of the '960 are crystalline; however the reference is silent to morphology of the particles. The '960 patent however need not teach each and every element of the instant claims in order to support or obviate the instant claims. The reference need only meet

the deficiencies of the '990 patent. The '960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, lin. 50-61). Carriers for the scaffold include further biocompatible polymers such as cellulose gums and gelatin (col. 12, lin. 15-35). The bioactive glass is coated on the surface of the polymers (col. 18, lin. 29-42), and the bioactive glass polymers comprise calcium and phosphorous molecules (co. 17, lin. 45-col. 18, lin. 9). From the figures it is clear the scaffold in orderly with the fibers being placed evenly apart in order to create a scaffold configuration (Figures).The fiber scaffold has a void fraction (porosity) of 20-90% (claim 2). It would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to ensure increase tissue growth and reaction upon implantation. It would have been obvious to combine the fibers of the '960 patent into the formulation of the '990 patent since both patent disclose bioglass composites comprising calcium and phosphorous molecules. The '990 patent is suggestive of bone growth upon implantation and the fibers of the '960 are specifically designed to optimize tissue ingrowth after implantation it would have been obvious to include the fibers into the sol-gel bioglass of the '990 patent in order to maximize new tissue growth.

With these things in mind it would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to increase the implants ability to react with surrounding tissue upon implantation, as well as encourage tissue in growth. The '960 patent teaches that the surface of the fiber mesh scaffold should be coated with bioactive glass for the expressed purpose of increasing tissue growth. The bioactive glass composite of the '990 patent accomplishes this end. It would have been obvious to combine the prior art in order to increase

tissue growth at the implantation site. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments. For these reasons the claims remain obviated.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612